A. Response to Utility Rejection under §§101 & 112

Claims 3 and 35-37 stand finally rejected under 35 U.S.C. §§101 and 112, for allegedly lacking patentable utility. In particular, the Examiner asserts that the claimed invention lacks either a specific or substantial asserted utility.

With regard to the issue of specificity, it seems that the Examiner is suggesting that identification of a protein as a member of the PDZ family is not enough; one must also disclose a ligand or specific PDZ binding partner for the protein.[1] However, we believe that this is not the test. The utility guidelines define a *specific* utility as a utility that is specific to the subject matter claimed (in contrast to a *general* utility applicable to the broad class of invention).

Applicants respectfully submit that the Examiner has too narrowly construed the phrase "broad class of the invention" to refer to the specific protein family (here the PDZ family). A more proper interpretation of the phrase "broad class of the invention", in the present case, is the class of "beta-proteins." As a member of the class of beta-proteins, a polypeptide comprising SEQ ID NO:1 has specific utility as a PDZ domain polypeptide that interacts with PDZ binding transmembrane proteins. PDZ binding transmembrane proteins comprise a well-established family of proteins and have been reported to play a role in signal transduction, particularly cell proliferation, neural transmission, apoptosis and malignant conversion. As such the polypeptides as claimed are valuable targets for developing pharmaceuticals.

With regard to the issue of substantiality, substantial utility is defined as "real world" use. In this case, a polypeptide of SEQ ID NO:1 has utility in assaying, detecting, and purifying PDZ binding proteins, a class of proteins having known biological significance. A protein need not directly correlate to a palpable physiological parameter such as "blood pressure, heart rate, taste, cognition, or sensation of pain" in order to be biologically useful. Rather, how a compound affects measurable cellular parameters such as cell proliferation, onset of apoptosis, and malignant conversion, is frequently correlated to physiological utility, such as treatment of cancer or proliferative disorders. Specific physiological utilities are readily apparent to those in the art from the measured properties.

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[1] In the Final Rejection, at the bottom of page 3, the Examiner states that "Applicant is *not* being required to identify a ligand for the protein, and a physiological process mediated thereby and a disease or disorder for which that protein is a marker". However, this is exactly what the Examiner appears to be requiring – a more stringent standard than that set forth by the utility guidelines.

In addition, Applicants submit that the present invention can be used for tissue typing and measuring tissue expression, a utility that is certainly specific, substantial, and well-established. The Utility Guidelines provide that a "gene probe" or "chromosome marker" is considered to be specific where a specific DNA target is identified. By analogy, the specification teaches that a polypeptide comprising SEQ ID NO:1 and 2 are specifically expressed in liver tissue, thereby providing a specific use to the subject matter claimed. Tissue markers are commonly used in research and diagnostics to identify cell types, as housekeeping markers, and the like. Support for this specific, credible, and well-established utility regarding the use of a polypeptide comprising SEQ ID NO:1 and 2 as a tissue marker can be found, for example, at page 7, lines 1-5; Example 5, beginning at page 46, pages 54-55; pages 62-63; and Figures 5, 6, 15, 16, and 19, and corresponding legends at pages 26-32. Accordingly, the polypeptides comprising SEQ ID NO:1 and 2 have a substantial, real-world use.

A credible utility is also provided by the use of a polypeptide comprising SEQ ID NO:1 and 2 in that the use of the polypeptide (or antibodies developed against the polypeptide) as a tissue marker is clearly believable, practical, and cannot be dismissed by one of skill in the art as "wrong". (See, e.g., page 5 of the "Revised Interim Utility Guidelines Training Materials".)

Thus, we believe that the specification, when read in light of the prior art, provides at least one specific, substantial, and credible well-established utility for the protein of claims 3 and 35-37.

Applicant asks that claims 3 and 35-37 be allowed. A check in the amount of $1152 is enclosed to cover the filing fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

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